

## **REMARKS**

Claims 1-18 and 20-90 are currently in the application. Claim 19 has been previously cancelled without prejudice to Applicant. Pursuant to a telephone conversation with the Examiner on February 12, 2003, a provisional election with traverse has been made to prosecute the invention identified by the Examiner as Group II, Claims 17-41, 45-47, 49-50, 53-54 and 70. The inventions of Group I, Claims 1-16, 42-44, 48, 51-52, 55-69, and 71-72 are thus presently withdrawn from further consideration with this application. Claims 73-90 continue to be presented for consideration with this application in accordance with remarks set forth below. Notwithstanding the foregoing, Applicant reserves the right to re-present any of the withdrawn claims for consideration upon any subsequent successful traverse of the Examiner's restriction requirement. Applicant further reserves the right to present the withdrawn claims in a continuation type application claiming the benefit of priority of this application.

Claims 73-90 are written to a method of linking an unknown composition to known compositions utilizing the steps of the method from the originally presented claims. Such a version of the method is clearly supported by the specification. As a result, no new matter was presented by the addition of Claims 73-90. The inventions of Claims 73-90 are not independent or distinct from the original claims, but rather are directed to a specific use of the method disclosed and originally claimed. As a result, withdrawal of these claims by the Examiner is entirely improper, and Applicant respectfully requests that the Examiner consider Claims 73-90 on the merits.

### Claim Rejections - §102

Claims 17-22, 25-33, 41, 45-47, 49-50, 53-54 and 70 are rejected under §102(b) as being anticipated by Welle. Applicant respectfully requests reconsideration of this rejection.

As previously pointed out to the Examiner in papers submitted for this application, the patent to Welle discloses a method for identifying materials using an artificial isotopic taggant composition that is *added* to the materials for retrospective identification of the materials using controlled abundance ratios of two or more isotopes of one or more elements in the taggant composition. Abundance ratios for each element are selected according to the Welle disclosure in order to provide a unique code to be assigned to a product batch or lot. The elements from the taggant composition are added to the product, and are thus essentially not an integral part of the product itself. For example, col. 2, lines 36-46 discloses adding ten different concentration ratios for the element europium to commercially prepared batches of explosives which do not normally or naturally contain europium in either elemental or compound form. Indeed, a distinct method of analysis is required for products that actually contain background traces or contamination of the selected tagging element, and so the teaching is clearly preferably biased toward the selection of elements not found in the product naturally or even that may be commonly found in the context of the intended use of the product.

The Examiner has cited Welle as disclosing an isotopic tagging method containing each of the claim limitations of the rejected claims. However, the Examiner has incorrectly identified certain steps of Applicant's claims as matching with and reading on the Welle disclosure. Specifically:

(1) “Analyzing a product for the concentration of isotopes (col. 2, lines 34-67, col. 3, lines 9-63)”. This is entirely incorrect and not found in Welle as recited by Applicant. Claim 17 specifically requires that a concentration of a plurality of naturally occurring stable isotopes in their natural or ambient concentration or in an enhanced concentration of the product itself be analyzed. The citation by the Examiner from Welle, in complete contrast, specifically states that artificially created isotopic ratios or spiked isotopic ratios for additive elements that are not naturally part of the product itself be analyzed. Indeed, Welle col. 2, lines 27-31, states that abundance ratios of isotopes are artificially controlled by purposeful addition to provide a means of identification. Also, col. 1, lines 15-26 summarizes the disclosure as use of an identification code consisting of unique taggants, each corresponding to a unique combination of ratios of multiple stable isotopes, created by mixing unique combinations of isotope ratios, the resulting mixture being “added to the substance or product to be tagged”. Col. 3, lines 12-17 discloses that the code can be expanded by adding to the product (“explosive” in the example) an additional element with its own specific set of concentration ratios of isotopes. Each taggant mixture, having been artificially created to correspond to a particular predetermined set of isotope ratios or “code”, is thus added to the product and constitutes the identifier, such as a brand, for the product batch. The isotopic ratios are thus predetermined for the “code”, and any analysis is to identify which predetermined ratio has been added to the product being tested.

In complete contrast, analysis of isotopes in Applicant’s invention constitutes determination of a random, naturally occurring (not predetermined) identifying factor, and is not the identification itself as in Welle. The identification in Applicant’s method occurs as a result of

the creation of the mathematical array generated from measured values of naturally occurring, not pre-determined, isotope ratios and concentrations in their natural or ambient concentrations or enhanced concentrations. Furthermore, not only do Applicant's claims recite analysis of isotopes of elements in the product itself (not simply any element added to the product), they also recite analysis of isotopic ratios occurring naturally in the product, not artificially or otherwise specifically altered by design. As a result, Welle does not in any way disclose the step of analyzing a product for the concentration of isotopes as has been specifically disclosed and claimed by Applicant. The disclosures and teachings therefrom are entirely distinct.

(2) "Arranging the concentrations of the isotopes in a mathematical array (table II, col. 2, lines 36-67)". The arrangement shown in Table II of Welle is in no way even similar to the array disclosed and claimed by Applicant. See Table I of the specification. Table II is a chart of pre-determined artificially determined ratios corresponding to a batch or serial number. Thus, each row corresponds to a specific identifier, and thus there are several identifiers in each such table. Table II thus contains a pre-determined code for 10 distinct identifiers. Similarly, Table III contains a predetermined code for 1,000 distinct identifiers. The Welle disclosure teaches how to create such code tables with as many distinct identifiers as desired.

In complete contrast, the mathematical array disclosed and claimed by Applicant (see Table I of the specification) which when taken as a set comprises a distinct, identifier, or several identifiers. The array is itself the identifier. Further, the columns of the array may identify excipients, components, or impurities and the whole array may identify the product. The simplicity or complexity of the array as disclosed in the specification can be altered to correspond

to various error tolerances (the more complexity, the less error). As recited in Claim 17, the concentrations of the isotopes analyzed are arranged in the mathematical array. Table II of Welle, on the other hand, shows a table listing several distinct identifiers, and is, essentially, a code key for the isotope ratios to be added to the product. Table II as a whole could not be used to identify any particular product, and is specifically not intended to do so. Instead, Table II shows nine specific isotope ratio identifiers on nine product batches based on selectively predetermined concentration ratios of elements added to, but not an intrinsic part of, the product. In contrast, the array disclosed by Applicant comprises values of naturally occurring isotope concentrations and/or ratios that identify or correspond to identification of one particular product. Thus, Applicant's array (a summary of what is naturally occurring) is clearly totally different from the code keys disclosed by Welle (a summary of what is spiked into the product) in light of the intended use as well as in light of the respective disclosures. The teachings regarding these arrays are entirely distinct.

The Abstract of Welle recites:

"A system for **tagging** products of substances for retrospective identification using [artificially-] **controlled abundance ratios** of multiple isotopes in each of on or more elements in the **tagged** substance. The abundance ratios of the isotopes of the **tagging** elements are measures by suitable means to determine the identification code of the **tagged** product of substance. Emphasis added.

To "persons skilled in the art" "tagging" means that something (*viz.* isotopes) was **artificially added** to identify the products. By contrast, the Applicant's patent application deals

solely with naturally-existing isotopes in their natural or ambient or enhanced concentrations – no tagging period.

(3) “Assembling product information (col. 1, lines 5-10)”. It is entirely unclear how col. 1, lines 5-10 of Welle disclose anything about assembling product information. This text comprises the “Background” section of the Welle patent disclosure and recites:

There is significant interest in tagging various substances or products such as explosives, ammunition, paint, and petroleum products to provide for retrospective identification. Methods used to date generally involve the addition of materials from one or more of three categories: code-bearing microparticles, bulk chemical substances, and radioactive substances.

In contrast, the product information disclosed by Applicant includes such things as ingredient identifications and formulations, or, for pharmaceutical products, physician directed information. Page 80, lines 11-13 of the Amendment paper filed June 26, 2003:

“The same analytical procedures can be used to identify other products, such as organic products, such as gunpowder and other explosives, crude oil, foodstuffs, petroleum distillates, hazardous waste, paper and/or ink, and tire materials.”

None of such product information or even like information is disclosed anywhere in Welle, and according to the method of Welle is not at all required as part of identifying any particular product.

(4) “Measuring the concentration of the isotope in a comparable substance and comparing the concentration of isotopes with the mathematical array to identify the product (col. 1, lines 15-26; claim 1)”. Although Welle discloses measuring and comparing steps for purposes of identification, it is the subject of the measuring and the concentrations being compared that are entirely distinct between Welle and Applicant’s disclosure. Welle discloses adding a mixture of

unique combinations of ratios of multiple stable isotopes of one or more elements, and measuring the abundance ratios of the taggant elements that are added to the product to be later identified. In contrast, no taggant is added to the product according to Applicant's disclosure. As a result, the measured concentrations are measured to compare not with a "tagging record" but rather with individual mathematical arrays that have been determined and generated according to measurements from a particular batch, or an index of such measurements corresponding each array to a particular batch. Indeed, there is no exogenous or artificial tagging that occurs according to Applicant's disclosure, and thus the identifying techniques are entirely distinct with respect to the "measuring" and "comparing" steps that are disclosed and taught by each. That is, Welle would add an isotopic spike of an exotic material to a given product, then measure the results and tabulate them for identification purposes. By contrast, the Applicant would simply measure given products' natural or ambient isotopic ratios, then measure the results and tabulate them for identification purposes. It must be stressed that the exotic tracer elements (Nd, Eu, etc.) in relatively huge isotopic-ratio differences that Welle would add would typically be distinctly different than the common "matrix" elements (e.g. C, N, O, H) that Applicant typically employs in their minisculely-small isotopic-ratio differences.

(5) "Isotopes are chosen based on errors, ratios and the combination of the two (col. 3, lines 1-24; col. 3, line 66-col. 4, line 16)". It is unclear what claim limitation the Examiner is referring to with this citation. Claim 20 and similarly reciting claims among the rejected claims recite that "concentrations of isotopes are chosen from the group of isotopic concentrations consisting of concentrations of isotopes, concentrations of isotopes and their errors, and ratios of

isotope concentrations, ratios of isotope concentrations and their errors and combinations thereof". Thus, the recitations are with respect to the concentrations which are arranged into the mathematical array, i.e. the specific information that is arranged in the array – isotopic concentration, concentration with measurement error listed, concentration ratios, ratios and errors, and any combination of these. The tables provided in Welle are code keys that list batch/serial numbers corresponding to isotope abundance ratios which were artificially added to the product. Thus, actual concentration, error, and combinations of any of the claimed limitations are not even considered by Welle in this regard. Rather, the discussion regarding errors and concentrations in Welle are with regard to measurement of isotope concentration and the technological capabilities of such measurements relating to selection of artificially predetermined abundance ratios, and have nothing to do with the actual use of such measurements and their errors as specific aspects of the method disclosed. Thus, the limitations of Claim 20 and the similarly reciting claims among those rejected are entirely distinct and have not been anticipated by this teaching from Welle.

(6) "The product information is made on a machine (col. 5, line 66-col. 7, line 22)". The citation to Welle is with regard to specific applications of that distinct method and has nothing to do with use of a machine, or storage of product information on a machine, as recited by Applicant. First, product information is not even discussed in Welle, as pointed out above. Second, there is no reference in Welle to the use of a machine to store any such information, as disclosed and claimed by Applicant.

In addition to the foregoing claim limitations that have been incorrectly matched by the Examiner with disclosures in Welle, the Examiner has further failed to identify disclosure in Welle



that anticipates the limitations of Claim 41 that identifies a group of mathematical array types, which limitations clearly remove any similarity between Applicant's disclosure and the tables of Welle cited by the Examiner. Similarly, the Examiner has failed to identify disclosure in Welle that anticipates the limitations of Claims 23 and 39 with regard to product information being printable from the memory on a machine.

In light of the several incorrect findings by the Examiner in determining that each of these claims have been anticipated by Welle, it is clear that the Examiner fails to understand the fundamental differences between the Welle method and the method disclosed by Applicant. Several of those differences have been pointed out above.

The primary difference which is also the most distinguishing is that Welle utilizes a mixture of taggant elements that have been purposely and selectively formulated to contain specific ratios of the stable isotopes for each element in the mixture. As identified in the "Background" section of that patent, the Welle method requires the addition of materials, and is fundamentally a method for specifically marking or branding batches of a product and keeping track of what batches were marked with what marking, i.e. taggant mixture, all the while maintaining a record of what taggant mixture corresponds to a serial number or other batch identifier.

In complete contrast, nothing needs to be added to the product according to the disclosure by Applicant. Isotopic concentration measurements are taken of selected elements that are naturally occurring in the product, not added to the product. Thus, the naturally occurring element isotope concentrations measured according to Applicant's disclosure exist as they naturally occur

within the product, and are not modified, enhanced, or otherwise artificially controlled. As each batch is made, the measurements are performed and a mathematical or other numerical array is created as the identifier for that batch. To identify a product at a later time as to its batch, the same measurements are performed from the product and a similar array created and compared to the identifier arrays previously generated, which then identify the product as having come from a particular batch. The only similarity between the technique taught by Welle and the method disclosed by Applicant is that both employ isotopic analysis and both use of previous analyses to compare against previously tabulated data. However, Welle uses artificially pre-determined isotopic ratios of added elements (usually exotic trace elements which the FDA would not allow to be added to pharmaceuticals or food), whereas Applicant uses mathematical arrays generated generally from measurements of naturally occurring isotopic concentrations and/or ratios of elements occurring naturally in the product (C, N, O, H, etc.), not subsequently added thereto. Thus, essentially every other aspect of the separate disclosures is completely different and patentably distinct.

#### Claim Rejections - §103

Reconsideration of the rejections of Claims 23, 24 and 34-40 under 35 U.S.C. §103(a) as being unpatentable over Welle in view of Brand et al. is respectfully requested.

The Examiner has failed to establish a prima facie case of obviousness for any of the claims rejected on this basis. In light of the foregoing remarks regarding Welle being incapable of anticipating, among others, independent Claim 17, on which each of these rejected claims are ultimately dependent, Welle as the primary reference clearly fails to provide each and every



element recited by the rejected claims. This is so even when combined with Brand et al., which is obviously and admittedly cited for a very narrow purpose that cannot overcome this deficiency. As a result, the references cited for these rejections fail to support any findings of obviousness, and thus each of the rejections on this basis should be withdrawn.

For all of the reasons stated above, Applicant respectfully submits that the application as amended is in form for immediate allowance upon examination of the added claims. Applicant respectfully solicits the prompt issuance of a Notice of Allowance.

Respectfully submitted,

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